
heart sure

Pulse Oximeter
A320

User Manual



Please keep this instruction manual in a safe place where it is readily available.

File No.: Fingertip-OPE V2019/09

Section 1

Safety

Read this section thoroughly before using the product. Please ensure you observe the safety instructions to avoid accidents, injury and damage.

1.1 Instructions for the Safe Operation and Use of the Pulse Oximeter

- Do not attempt to service the Pulse Oximeter yourself. Only qualified service personnel should attempt any necessary internal servicing.
- Do not use the device for prolonged periods of time. It is designed for spot-check use only.
- Do not use in ICU or high-care environments.
- SpO₂ measurements may be adversely affected in the presence of high ambient light. Shield the sensor area if necessary.
- The following will cause interference to the testing accuracy of the Pulse Oximeter:
 - High-frequency electrosurgical equipment.
 - Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
 - Patients with hypotension, severe vasoconstriction, severe anaemia or hypothermia.
 - The patient is in cardiac arrest or is in shock.
 - Fingernail polish or false fingernails may cause inaccurate SpO₂ readings.

1.2 Warnings

WARNING: This product is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience and knowledge, unless they have been given supervision or instruction concerning use of the appliance by a person responsible for their safety.

WARNING: Keep the product, batteries and its components out of reach of children. Keep children away from the packaging material. DO NOT let children play with the product.

WARNING: EXPLOSION HAZARD Do not use the Pulse Oximeter in a flammable atmosphere where concentrations of flammable products exist.

WARNING: Do not throw batteries in fire as this may cause them to explode.

WARNING: Do not attempt to recharge normal dry-cell batteries as they may leak, cause a fire or explode.

WARNING: Do not use the Pulse Oximeter in an MRI or CT environment.

WARNING: Do not modify this equipment without authorisation of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.

CAUTION: Do not operate the unit if it is damp or wet. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

CAUTION: The batteries must be taken out from the battery compartment if the device will not be used for more than 12 months.








CAUTION: The device should only be used if the battery cover is closed.

CAUTION: Periodically check batteries to ensure they are in good working condition. Replace worn batteries with new ones immediately. Dispose of the old batteries according to current local regulations

CAUTION: Only use batteries specified for the product. Do not use batteries after their expiration date; or new and used batteries together; or different brand batteries together.

CAUTION: If battery fluid gets into your eyes or touches your skin, immediately rinse with plenty of water and consult a healthcare professional.

1.3 Definitions and Symbols

Symbol	Description
	Type BF Equipment
SN	Serial Number
	Information of manufacture, including name and address
	Temperature limitation
	Humidity limitation
	Air Pressure limitation
	At the end of its life, please treat this product as electronic waste and dispose of responsibly according to current local regulations.
	Follow instruction for use
IP22	Solid particle & liquid ingress protection rating

<i>Warning</i>	Improper use may cause danger resulting in death or serious injury. These are situations in which the device should not be used.
<i>Caution</i>	Indicates a potentially hazardous situation which, if not avoided, may result in injury to the user or patient or damage to the equipment or other property.
<i>Note</i>	The important information you should know

Section 2

Introduction

2.1 General

This chapter provides a general description of the Pulse Oximeter including a brief device description and product features.

2.2 Brief Device Description

The Pulse Oximeter is intended for non-invasive spot-check measurements of functional oxygen saturation of arterial haemoglobin (SpO₂). The advanced DSP algorithm can minimize the influence of motion and improve measurement accuracy of low perfusion.

The Pulse Oximeter can be used to measure human oxygen saturation and pulse rate through the finger. The product is suitable for use by individuals and healthcare professionals in multiple situations, including; home, clinical & sporting environments. For example:

- Pre/post-exercise.
- Pre/post-operative conditions.
- Monitoring respiratory conditions.

2.3 Product Features

- Measures oxygen saturation (SpO₂) and pulse rate (PR).
- Lightweight & portable.
- Easy to use.
- Manually adjust the direction of interface (6 display modes).

- Dual colour OLED display, simultaneous display for testing value and plethysmograph[^].
- Low perfusion: 0.3%.
- Anti-shaking technology.
- Visual & sound notification function.
- Real-time spot-checks.
- Low battery voltage indicator.
- Automatic switch off.
- Standard 2x AAA 1.5V Alkaline batteries will provide more than 20 hours continuous output.

CAUTION: The device cannot be used in children less than 1 year old as the result may not be accurate.

CAUTION: The fingertip Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

2.3.1 [^] Definitions

[^] **DSP algorithm:** Digital signal processor algorithm.

[^] **Low perfusion:** In physiology, perfusion is the process of a body delivering blood to a capillary bed in its biological tissue. Under the condition of low perfusion, the measurement of non-invasive saturation of pulse-blood oxygen can be low.

[^] **Plethysmograph:** Instrument for measuring changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains).

Section 3

Installation, Setup and Operation

3.1. Description of the Front Panel (as figure 3.1.1)



Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Name and Description

Item	Name	Description
1	Power Button	Turn on/off the machine
2	Direction Button (M)	Direction change & parameter setting within the menu
3	Battery Compartment	Compartment for batteries
4	OLED Panel	Displays the SPO2/PR data & Plethysmograph

3.2 Display

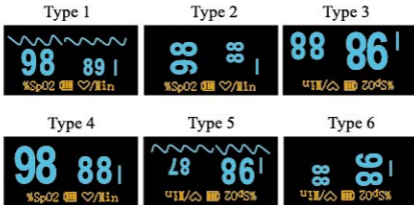
After being switched on, the OLED display is as follows:



Figure 3.2.1 OLED display

3.2.1 Display Modes

The OLED display can rotate four directions with six different display modes when pressing the direction button (M) as shown below:



3.3 Operation

3.3.1 Install battery

Remove cover & install 2 x AAA batteries into the battery cassette in correct polarities and place cover back on.



3.3.2 Turn the Pulse Oximeter On

Press the power button for 2 seconds to turn the Pulse Oximeter on. Open the clamp, then place one finger into rubber hole of the Pulse Oximeter (it is best to put the finger as far in as possible) with nail surface upward, then release the clamp to shut.



3.3.3. Read data on the display screen

The data may take a few seconds to appear while a reading is obtained. Only your Healthcare Professional can interpret your individual readings.

3.3.4. Parameter Settings

In the parameter settings menu you can set high/ low notification values for both SpO2 and PR, as well as turning sound on/off. To access the parameter settings hold down the (M) button for one second.

There are two types of submenus; Notify Setup and Sounds Setup. To switch between the setups, ensure the * is next to the word Sounds Setup or Notify Setup, then press (M) for one second to switch between menus, as per figures 3.3.1 and 3.3.2.

3.3.4.1. Sounds Setup

Hold down the (M) button for one second to bring up the sound menu as per figure 3.3.1. Press (M) quickly to move down the menu.

To increase parameter values

Press (M) quickly to move down the menu until your * signal appears next to the + / - sign. Then hold down (M) for one second until the + sign appears. This will now increase the value of any parameter in this menu. Quickly press (M) to move to the parameter value you wish to change. Once you have reached the parameter value you want to change, hold down (M) for one second and you will see the value increase. Once you've reached your desired level, release the (M) button.

To decrease parameter values

Press (M) quickly to move down the menu until your * signal appears next to the + / - sign. Then hold down (M) for one second until the - sign appears. This will now decrease the value of any parameter in this menu. Quickly press (M) to move to the parameter value you wish to change. Once you have reached the parameter value you want to change, hold down (M) for one second and you will see the value decrease. Once you've reached your desired level, release the (M) button.

3.3.4.2. Notification Setup

Hold down the (M) button for one second to bring up notification menu as per figure 3.3.2. Press (M) quickly to move down the menu.

To turn Sound Notification or Beep ON

Press (M) quickly to move down the menu until your * signal appears next to the word Sound Notify or Beep. Then hold down (M) for one second until the word *on* appears.

To turn Sound Notification or Beep OFF

Press (M) quickly to move down the menu until your * signal appears next to the word Sound Notify or Beep. Then hold down (M) for one second until the word *off* appears.

3.3.4.3. To Exit Parameter Settings Menu

Press (M) quickly to move down the menu until your * signal appears next to the word Exit. Then hold down (M) for one second to exit menu.

3.3.5 Restore Back to Original Factory Settings

In the Notify Setup menu, press the (M) quickly to move down the menu until your * signal appears next to word Restore. Then hold down (M) for one second until word OK appears. This will then restore the device back to its original factory settings.



Figure 3.3.1

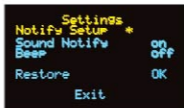



Figure 3.3.2

Note: 1. The notification sound has a 1 second delay after an incorrect result is detected.

3.3.6 Turn the Pulse Oximeter Off

Press & hold the power button for 2 seconds. Alternatively the device will automatically shut off after approximately 10-15 seconds.

- Note:** 1. When the battery power is at lowest level, the battery indicator symbol "" appears, indicating replacement of battery is required.
2. The plethysmograph can be regarded as correct if the wave is fluctuating constantly.

Section 4

Cleaning and Disinfection

4.1 Cleaning & Disinfection

Switch off the power and take out the batteries before cleaning. Keep the surface of the device clean and free of dust and dirt. Clean the surface (OLED display screen included) of the unit with a soft dry cloth. Disinfect the machine if being used in a clinical setting or by multiple users. To disinfect, use a small amount of 70-75% density medical alcohol on a soft dry cloth to avoid alcohol permeating into the device.

CAUTION: Do not use strong solvent. e.g acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquid on the device while cleaning.

CAUTION: Do not leave any cleaning solution on the surface of the device.

Section 5

Troubleshooting and Maintenance

5.1 Maintenance

- Replace the batteries when the battery indicator symbol is low.
- Clean/disinfect surface of the Pulse Oximeter before use.
- Remove the batteries inside the battery cassette if the Pulse Oximeter will not be operated for more than 12 months.
- Store the product in a place where ambient temperature is -10 to 50°C and humidity is 15% to 80%.
- Regularly inspect the device to make sure that no obvious damage exists that will effect the safety and performance of device.

5.2 Troubleshooting

Table 5.2.1 Troubleshooting

Problems	Possible Reason	Resolutions
Oxygen saturation or pulse rate is reading abnormally.	1. Finger is not placed correctly.	1. Retry by placing the finger in the correct position as per instructions.
	2. Patient's perfusion is too low to be measured.	2. Retry the measurement, if still reading abnormally, please consult healthcare professional.
Oxygen saturation or pulse rate is unstable	1. Finger is not placed correctly.	1. Retry by placing the finger in the correct position as per instructions.
	2. Finger is trembling or patient is moving.	2. Ensure patient is not moving during measurement.

Problems	Possible Reason	Resolutions
Oxygen saturation or pulse rate is abnormal and caused notification to sound.	1. Finger is not placed correctly.	1. Retry by placing the finger in the correct position as per instructions.
	2. Patient's SpO ₂ & PR is abnormal.	2. Please consult healthcare professional.
Pulse Oximeter does not turn on.	1. There maybe inadequate power left in the batteries.	1. Please replace batteries.
	2. Batteries may have been installed incorrectly.	2. Please re-install the batteries.
	3. The Pulse Oximeter may be damaged.	3. Please contact local customer service center.
The device automatically turns off.	1. The product is automatically powered off when no signal is detected longer than approx. 10-15 seconds.	1. This is normal.
	2. There maybe inadequate power left in the batteries.	2. Please replace the batteries.

Section 6

Specifications

Pulse Oximeter Specifications:

Physical Characteristics

Machine

Dimensions : 37mm (W)× 74mm (D) × 38mm (H)

Weight : approx: 50g (including 2×AAA battery)

Retail package

Dimensions: 90mm (W) × 120mm (D) × 67mm (H)

Gross Weight: 175g

Classifications:

Anti-electric Shock Type: Internally powered equipment

Anti-electric Shock Degree: Type BF equipment

EMC: Type B

Mode of operation: Continuous Operation

IP22

The first digit indicates the level of protection that the enclosure provides against access to any hazardous parts and the ingress of solid foreign particles.

2 = protection against particles >12.5 mm

The second digit indicates the level of protection that the enclosure provides against the harmful ingress of water.

2 = protection against dripping water when tilted up to 15°

Power

Internal	2 x 1.5V AAA [LR03] battery
Power Consumption	Less than 30mA(Normal)

Operation Environmental Condition:

Operating Temperature	5°C to 40°C
Relative Humidity	15% to 80% non-condensing
Air Pressure	86kPa-106kPa
Operating Altitude	0-2000 m

Transportation and Storage Environmental Condition:

Storage Temperature	-10°C to 50°C
Relative Humidity	10% to 80% non-condensing
Air Pressure	60kPa-106kPa
Operating Altitude	0-2000 m

Alarm default value

Parameter	Value
Oxygen Saturation	Upper limit: 100 / Lower limit: 90
Pulse Rate	Upper limit: 130 / Lower limit: 50

Probe LED Specification

	Wave Length	Radiant Power
RED	660±2 nm	1.8 mW
Infra RED	905±2 nm	2.0 mW

Electronics Parameters

Parameter		Value
Oxygen Saturation Display		35-100%
Pulse Rate Display		30-250 BPM
Resolution	Oxygen Saturation	1%
	Pulse Rate	1 BPM
Measure Accuracy	Oxygen Saturation	$\pm 3\%$ (70%-100%) unspecified(< 70%)
	Pulse Rate	± 1 BPM

Manufacturer's Declaration of the EMC

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS


1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	RF emissions CISPR 11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	N/A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity	
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycles	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pulse Oximeter requires continued operation during power mains interruptions, it is recommended that the Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a. c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity
 –for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF	3 Vrms	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	6Vrms in ISM bands between 150 kHz to 80 MHz	10 V/m	
IEC 61000-4-3	80 MHz to 2.7 GHz		
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.			

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Oximeter.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the Pulse Oximeter

The Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter / m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Warranty Information

PRODUCT WARRANTY

Please register your warranty information at:
AUS-www.jadavey.com.au
NZ- www.jadavey.co.nz

This product is warranted to be free of manufacturing defects for 2 years from the date of purchase. This warranty is void if the product is modified or altered, is subject to misuse or abuse; damaged in transit; lack of responsible care is dropped; if damage occurs by reason of failure to follow the written instruction booklet enclosed; or if product repairs are carried out without authority from J.A.Davey Pty Ltd.

We will repair, or at our option replace free of charge, any parts necessary to correct material or workmanship, or replace the entire unit and return to you during the period of the warranty. Otherwise, we will quote for any repair which will be carried out on acceptance of our quotation. The benefits conferred by this warranty are in addition to all other rights and remedies in respect of the product, which the consumer has under the trade practices act and other state or territory laws in Australia and New Zealand.

Our goods come with guarantees that cannot be excluded under the Australian and New Zealand Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

Before you send in your unit for service

Before sending in your unit for service, please take a few minutes to do the following:

- In your user manual, read the troubleshooting section in regards to common problems, possible reasons and resolutions.
- Contact Heart Sure Customer Service. Our staff are trained to assist you with most issues you may experience, without the need to send your product in for service.

Sending in your unit for service

1. Should repair be needed within the warranty period, enclose the tear off section of this warranty card and your proof of purchase receipt. Please ensure all relevant details are completed before sending your unit in for service. Please ensure your contact details are current and include a brief description of the problem you are experiencing together with your proof of purchase.
2. Include the unit with all product components in your package. This is extremely important, as it will assist our repair technicians in making the correct diagnosis of any problems.

**Please return the unit & warranty card
at your cost to:**

IN AUSTRALIA

J.A.Davey Pty Ltd- Heart Sure Repairs
PO Box 84
Port Melbourne
Victoria Australia 3207

IN NEW ZEALAND

BV Medical - Heart Sure Repairs
Unit 7, 110 Mays Road
Onehunga, Auckland, New Zealand,1061

**Should you require any further information
please do not hesitate to contact us by
calling our toll free number:**

IN AUSTRALIA

Free call:
1800 807 464

IN NEW ZEALAND

Free call:
0800 523 583





**PLEASE RETAIN THIS WARRANTY CARD.
RETURN THIS PORTION ONLY WHEN YOU RETURN
YOUR PRODUCT FOR REPAIR UNDER WARRANTY.**

NAME: _____

ADDRESS: _____

POSTCODE: _____

DAYTIME TELEPHONE: _____

EMAIL: _____

MODEL: _____

DATE OF PURCHASE: _____ / _____ / _____

ATTACH PROOF OF PURCHASE

RETAILERS NAME: _____

RETAILERS ADDRESS: _____

_____ RETAILERS POST CODE: _____

BRIEF DESCRIPTION OF PROBLEM YOU ARE EXPERIENCING:

WARRANTY IS VOID UNLESS THE ABOVE INFORMATION IS COMPLETED AND CORRECT.



Pulse Oximeter

IN AUSTRALIA:

J.A.DAVEY PTY LTD

Telephone: 1800 807 464

Website: www.jadavey.com.au

IN NEW ZEALAND:

J.A.DAVEY LTD

C/- Healthcare Logistics

Telephone: 0800 523 583

Website: www.jadavey.co.nz